REMARKS

Claims 1-74 are pending. Claims 34 and 44-74 have been withdrawn from consideration as being directed to a non-elected invention. Accordingly, claims 1-33 and 35-43 are under examination in the above-identified application. Claim 1 has been amended above. Support for the amendment can be found throughout the application and, for example, at page 36, lines 16-31. Accordingly, the amendments do not raise an issue of new matter and entry thereof is respectfully requested. Applicant has review the rejections set forth in the Office Action mailed December 15, 2003, and respectfully traverse all grounds for the reasons that follow.

With regard to the maintenance of the restriction and election of species requirement, Applicant respectfully requests reconsideration and rejoinder of some or all of the groups of claims. As set forth in Applicant's previous response, examination of the some or all of the groups of claims does not pose a serious burden on the Examiner. If the Examiner decides upon reconsideration that the restriction is to be maintained, Applicant respectfully requests a "second-eye review" as now implemented under the Restriction Practice Action Plan. Under the Action Plan, rejoinder practice is viewed favorably when examination of claims together would not pose a serious burden on the Examiner.

Applicant would like to thank Examiners Smith and Marschel for extending a personal interview with Applicant's representatives on March 24, 2004. As recorded in the Interview Summary, the rejection under 35 U.S.C. §§ 101 and 102 were discussed. The amendments above and remarks below are believed by Applicant to substantially conform to the subject matter discussed during the interview. Applicant respectfully requests the Examiner's reconsideration and withdrawal of these rejections.

Objection to the Title

The title has been objected to allegedly because it fails to be clearly indicative of the claimed invention. The Office asserts that the title is directed to multiparameter integration methods for the analysis of biological networks, whereas in contrast the claims are directed to a method of predicting a behavior of a biochemical system.

Applicant submits that the title is clearly indicative of the elected claims. For example, steps (a) and (b) compare and identify correlative changes in value sets between two or more data integration maps consisting of at least two networks of a biochemical system. The networks are biological networks and the claimed comparison and identification of correlative changes constitute an analysis. Finally, the data integration maps constitute a multiparameter integration. Accordingly, the title clearly indicates the claimed invention.

Rejections Under 35 U.S.C. § 101

Claims 1-33 and 35-43 stand rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. The Office asserts that the claims appear to lack a physical result performed outside the computer or directed to a practical application in the technological arts. The Office relies on the M.P.E.P. §§ 2106 (IV)(B)(2)(b)(i) and (ii) as authority for these alleged requirements.

Applicant submits that the claims as filed are directed to subject matter satisfying the statutory requirements § 101. The M.P.E.P. sections quoted in the Office Action are safe harbors for assessing statutory subject matter for computer-related process inventions. In fact, the heading of the first two quoted sections in the Office Action is entitled "Safe Harbors" for statutory process claims. The first quoted paragraph describes the safe harbor provision for "Independent Physical Acts" and the second quoted paragraph describes the safe harbor provision for "Manipulation of Data Representing Physical Objects or Activities." Thus, the quoted sections are directed to subject matter that is clearly statutory. For example, the first paragraph quoted for § 2106 (IV)(B)(2)(b)(i), states:

> Thus, if a process claim includes one or more post-computer processing steps that result in a physical transformation outside of the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

Office Action at page 6 (emphasis added); M.P.E.P. § 2106 (IV)(B)(2)(b)(i).

The third M.P.E.P. paragraph quoted in the Office Action, § 2106 (IV)(B)(2)(b)(ii), sets forth as an alternative that a computer-related process directed to a practical application in the technological arts constitutes established statutory computer-related

subject matter. This section, entitled "Computer Related Processes Limited to a Practical Application in the Technological Arts," also admonishes against evaluation of form over substance when assessing statutory subject matter when it states:

> What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application.

Office Action at page 7 (citation omitted).

Apparent from the cited M.P.E.P. sections in the Office Action is the absence of the paragraph setting forth and describing the authority most applicable to the claimed invention on statutorily patentable algorithms. In this regard, the Federal Circuit held in *State Street v. Signature Financial Group*, 149 F.3d 1368, 47 U.S.P.Q.2d 1596 (1998), 525 U.S. 1093, (1999) (cert. denied) that a claim to a data processing system was statutory subject matter when the system produced a concrete, tangible and useful result. Similarly, the subsequent holding of *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999), reaffirming *State Street*, also is not relied on by the Office to assess whether the claimed subject matter is statutorily patentable. *AT&T* held that a claimed computer process was statutory because the produced value was a useful, non-abstract result that represents information about a telecommunication call. *Id.* at 1358.

The M.P.E.P. § 2106 (IV)(B)(2)(b)(ii) provides guidance to Office Examiners for the application of the *State Street* and *AT&T* holdings when it states:

> For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. . . . A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) . . . For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

Id. at para. 4.

As described below, the claimed subject matter satisfies the statutory requirements for patentable subject matter. In this regard, the claimed subject matter has a practical application because it produces a useful, non-abstract result representing information about a thing as held in *AT&T*, or a useful, concrete and tangible result, as held by the *State Street* court. The claimed invention also satisfies the safe harbor guidelines enumerated in the M.P.E.P. because it can produce a physical result outside the computer M.P.E.P. § 2106 (IV)(B)(2)(b)(i).

The claimed invention is directed to a method of predicting a behavior of a biochemical system. The method consists of comparing two or more data integration maps of a biochemical system and identifying correlative changed in at least two value sets between the two or more data integration maps. As described at, for example, page 8, lines 3-8 and at page 9, lines 5-10, predicting a behavior of a biochemical system produces a useful, non-abstract result representing information about a biochemical system because the information results in models or rules that have a wide range of diagnostic or therapeutic applications. Similarly, the methods of the invention produce a useful, concrete and tangible result because the comparison and identification of correlative changes between data integration maps obtained under different conditions identifies actual changes in components of the biochemical system which, as described above, are useful to diagnose diseases or intervene therapeutically. The actual changes are concrete and tangible because they are measurements of changed levels or interactions between, for example, a normal and a perturbed state such as a disease.

For example, the application describes at, for example, page 19, lines 26-30, that a correlative change is intended to mean "a change in or alteration in a reference value set that is associated with a changed condition of a biochemical or constituent system, where a value set means two or more types of data elements that characterize a component of biochemical system (page 18, lines 27-29, for example). A component is defined at, for example, page 18, lines 25-28, to mean "a molecular constituent of the biochemical system, network or pathway, such as, for example, a polypeptide, nucleic acid or other macromolecule or other biological molecule." Therefore, the claimed invention is directed to statutory subject matter because in results in a practical application as held in *AT&T* and *State Street* and as summarized in M.P.E.P. § 2106

(IV)(B)(2)(b)(ii). Accordingly, this ground of rejection is respectfully requested to be withdrawn.

Claims 1-33 and 35-43 also stand rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter because the claimed method allegedly manipulates numbers, abstract concepts or ideas, or signals representing these such manipulations. The Office asserts that a process consisting solely of a mathematical operation, without some claimed practical application such as executing a mathematical algorithm, is not statutory subject matter.

Applicant submits that the claimed methods are statutorily patentable. In this regard, the previous judicial exclusion and the Freeman-Walter-Abele test, applied to identify unpatentable mathematical algorithms, was put to rest in *State Street*, when the Federal Circuit clarified that:

> Unpatentable mathematical algorithms are identifiable by showing that they are merely abstract ideas constituting disembodied concepts or truths that are not "useful." From a practical standpoint, this means that to be patentable an algorithm must be applied in a "useful" way.

State Street, 149 F.3d at 1373 & n.4

In holding that the transformation of financial data by the claimed system constitutes a practical application of a mathematical algorithm, formula or calculation, because it produces "a useful, concrete and tangible result," the *State Street* court further explained that:

> [A]fter *Diehr* and *Alappat*, the mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless, its operation does not produce a "useful, concrete and tangible result.

Id. at 1374 & n.7 (citations omitted).

As described previously, the invention is directed to a method of predicting a behavior of a biochemical system. Such predictions are practical because they can be used, for example, for the diagnosis of diseases or therapeutic intervention to treat a disease. The acts of comparing two or more data integration maps of a biochemical system obtained under different conditions and identifying correlative changes in at least two value sets that predict a behavior of the biochemical system similarly is a useful, concrete and tangible result because it results in a

data integration map that describes the characteristics of a biochemical system induced by two or more different conditions. The characteristics described in the resultant integration map can be used, for example, to diagnose diseases or identify points of therapeutic intervention for treatment of a disease. Therefore, the claimed invention does not consist solely of a mathematical operation without a claimed practical application as held by the *State Street* court. The invention not only manipulates values but it also compares integration maps consisting of these values as well as identifies correlative changes that predict a behavior of a biochemical system. Accordingly, the claimed methods are directed to statutory subject matter. Withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 112

Claims 1-33 and 35-42 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Office asserts that claim 1 lacks an antecedent basis for the phrase "said data integration map." Claims 16 and 32 stand rejected for indefiniteness for reciting the phrase "said value sets" allegedly because it is unclear whether the value sets in step (b) are perturbed or identical to the value sets of step (a). Claims 30 and 432 are alleged to be unclear with respect to repeating steps (b) and (c). The Office asserts that such a repetition will produce multiple second data integration maps and that it is unclear what correlation is determinative of the comparison of part (c).

Claim 1 has been amended above to recite that each of the data integration maps comprise at least two networks. Although clear as filed, the claim now expressly recites that each of the data integration maps contain at least two networks. Accordingly, this ground of rejections is moot and is respectfully requested to be withdrawn.

Regarding claims 16 and 32, the application defines a "value set" at, for example, page 17, lines 26-28, to mean a set of two or more types of data. Therefore, the term refers to the type of data element rather than the magnitude or change in value of the data type. In light of this defined meaning, the reference in step (b) to the value set as recited in step (a) refers to the same type of data which constitutes the first and second integration or interaction maps being compared, rather than magnitude of the data. Accordingly, the use of the term "value set" in

claims 16 and 32 is sufficiently clear and definite to distinctly claim the invention and withdrawal of this ground of rejection is respectfully requested.

Regarding claims 30 and 42, Applicant submits that the claims are clear as written. Claims 30 and 42 claim more than one iteration and identification of correlative changes between the first data integration or physical interaction map and a second map. Further iterations and identifications based on a subsequently generated map does not render claims 30 and 42 unclear. In this regard, each production of a second data integration map or physical interaction map based on a perturbation and identification of correlative changes, as recited in steps (b) and (c), predicts a behavior of the biochemical system. Accordingly, claims 30 and 42 are sufficiently clear and definite to distinctly claim the invention and withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1-33 and 35-42 stand rejected as allegedly anticipated by Stoughton et al. (U.S. 6,351,712). The Office asserts that Stoughton et al. describe comparing microarray profiles which are asserted to constitute data integration maps. The profiles also are asserted to consist of value sets of data elements of various behaviors such as gene expression levels, mRNA abundance and protein expression levels.

The application describes and claims comparing two or more data integration maps of a biochemical system, obtained under different conditions, and containing at least two networks. Correlative changes are identified in at least two value sets between the data integration maps where the identified correlative changes predict a behavior of a biochemical system. As described previously, a value set means two or more types of data elements that characterize a component of biochemical system (page 18, lines 27-29, for example). A component is defined at, for example, page 18, lines 25-28, to mean "a molecular constituent of the biochemical system, network or pathway, such as, for example, a polypeptide, nucleic acid or other macromolecule or other biological molecule." Therefore, the invention describes and

claims identification of correlative changes in at least two value sets between the compared integration maps.

Stoughton et al. appear to describe methods for analyzing mircoarray data. The data analyzed between compared microarrays consists of only a single type of data, namely, gene expression data. For example, all of the Figures and the Examples appear to describe the analysis of expression profiles only. The description at column 1, lines 14-27, and 38-41, cited by the Office does not describe comparing and identifying correlative changes in at least two value sets. Instead, these descriptions appear to describe various constituents that can be profiled. However, absent a description of an integration map and identification of correlative changes between two or more value sets containing two or more different types of data, Stoughton et al. cannot anticipate the claimed invention. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Claims 1-33 and 35-42 stand rejected as allegedly anticipated by Rine et al. (U.S. 5,777,888). The Office asserts that Rine et al. describe a method for generating and analyzing an output signal matrix to an output signal matrix database for correlating candidate stimuli and responses. The method is asserted to be used with an array of responder of living thing for drug testing to identify compounds with a particular effect.

As with Stoughton et al., Rine et al. similarly appear to describe a method for analyzing only a single type of data. The data analyzed corresponds to gene expression data in a matrix system. For example, the relevant passages and phrases in all the Figures and Examples appear to refer to profiles or gene expression profiles. Absent a description of an integration map and identification of correlative changes between two or more value sets containing two or more different types of data, Rine et al. cannot anticipate the claimed invention. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

Respectfully submitted,

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